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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 08/736,267      | 10/24/1996  | KJELL G. E. BACKSTROM | 06275/004001        | 3709             |

26161 7590 06/26/2003

FISH & RICHARDSON PC  
225 FRANKLIN ST  
BOSTON, MA 02110

| EXAMINER |
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LUKTON, DAVID

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1653

DATE MAILED: 06/26/2003

56

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/736,267

Applicant(s)

BACKSTROM ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-16,21,22,26,27,29-32,50-87,89-97 and 101-119 is/are pending in the application.
- 4a) Of the above claim(s) 61-77 and 79 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-10,12-16,21,22,26,27,29-32,50-60,78,80-87,89-97 and 101-119 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 56.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Pursuant to the directives of paper No. 54 (filed 3/24/03), claims 4, 21, 27, 56, 81 and 105 have been amended. Claims 1, 3-10, 12-16, 21, 22, 26, 27, 29-32, 50-87, 89-97, 101-119 are pending. Claims 61-77 and 79 remain withdrawn from consideration. Claims 1, 3-10, 12-16, 21, 22, 26, 27, 29-32, 50-60, 78, 80-87, 89-97, 101-119 are allowable.

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In the Office action mailed 12/30/99 (paper No. 35), claims 1-10, 12-16, 61-77, 101 were subject to restriction as follows:

I. Claims 1, 3-10, 12-16, 101, drawn to a composition which does not contain a "non-hygroscopic additive", classified in, e.g., 514/002.

II. Claims 1-10, 12-16, 61-77, 101, drawn to a composition which must contain a "non-hygroscopic additive", or alternatively must contain a carrier comprising particles having a diameter of at least 20 microns (as recited in claim 61) classified in, e.g., 514/002.

In paper No. 25 (filed 4/21/00), applicants elected Group I **without traverse**. At the present time, each of claims 61-67 and 79 is encompassed within Group II. What is sought in response to this Office action is cancellation of claims 61-67 and 79.

As indicated above, the election (filed 4/21/00) was made without traverse.

Accordingly, no further justification for the (previously imposed) restriction is required.

Nevertheless, the distinction between claim 1 and each of claims 61-67 and 79 is considerable. First, claim 1 precludes the presence of a propellant. Claim 61, by contrast, permits a propellant to be present. Second, claim 1 imposes the significant limitation that the composition **consist of** the peptide and the surfactant. In addition, the surfactant of claim 1 is limited to a very small subgenus. By contrast, claim 61 permits any enhancer to be present, whether a surfactant or not. In addition, claim 61 permits any other compounds to be present. In addition, the carrier of claim 61 is not limited in any way. Accordingly, the carrier of claim 61 could be, or contain peptide particles of 500 micron diameter, or 1000 micron diameter. Thus, claim 61 would encompass compositions in which 99.999999% of the particles are of any size. The differences between claim 1 and claim 61 are quite considerable. In addition to the foregoing, claim 61 does not "define a contribution" over the prior art. It appears that various references already of record (e.g., Office actions mailed 7/14/00 and 4/5/01) would anticipate, or render obvious, the subject matter of claim 61.

Thus, for a variety of reasons, the restriction mailed 12/30/99 remains justified.

What is required in response to this Office action is cancellation of claims 61-67 and 79, or other action by applicants as deemed appropriate.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle* [1935 C.D. 11, 453 O.G. 213].

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 6/29/03

Christopher S. F. Low

CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800